

INDUSTRY CIRCULAR

DEPARTMENT OF
THE TREASURY

Bureau of Alcohol, Tobacco and Firearms

Washington, D.C. 20226

Number: 76-17

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USE OF CHLOROFORM AS AN INGREDIENT IN HUMAN DRUG AND COSMETIC PRODUCTS

Manufacturers of Nonbeverage Products,
Users of Specially Denatured Alcohol,
Reprocessors of Specially Denatured
Alcohol Articles, and Others Concerned:

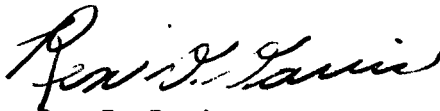
Purpose. This circular is issued to inform industry members that the U. S. Food and Drug Administration (FDA) has issued final regulations concerning the use of chloroform as an ingredient in human drug and cosmetic products and to advise manufacturers of articles made with specially denatured alcohol or rum and manufacturers of nonbeverage products of the action to be taken with respect to ATF Form 1479-A, Formula for Article Made with Specially Denatured Alcohol or Rum, or ATF Form 1678, Formula and Process for Nonbeverage Product, as appropriate.

Background. On June 29, 1976, the FDA published in the Federal Register final regulations concerning chloroform which become effective July 29, 1976. Human drug and cosmetic products containing chloroform as an ingredient that are introduced or delivered for introduction into interstate commerce after July 29, 1976, will be subject to regulatory action by the FDA. The new regulations require any holder of an approved "new drug application," or any sponsor of a "Notice of Claimed Investigational Exemption of a New Drug" (IND Notice), for a drug product containing chloroform as an ingredient to submit a supplemental application or amend his IND Notice on or before July 29, 1976, to provide for a revised formulation removing chloroform as an ingredient. Human drug and cosmetic products containing chloroform in residual amounts from its use as a processing solvent during manufacture, or as a byproduct from the synthesis of an ingredient, are not considered by the FDA to contain chloroform as an ingredient.

Compliance. In view of the above, effective immediately, formulas which are filed on ATF Form 1479-A or ATF Form 1678 calling for the use of chloroform as an ingredient in human drug or cosmetic

products will not be approved by the Director, Bureau of Alcohol, Tobacco and Firearms. Holders of existing approved formulas on ATF Form 1479-A or ATF Form 1678 which provide for the use of chloroform as an ingredient in cough preparations, liniments, or other human drug or cosmetic products must request cancellation of such formulas on file and reformulate these products removing chloroform as an ingredient. Manufacturers of nonbeverage products are reminded that in order to effect any amendment, revision, or restatement of an approved formula, a new formula, bearing a new serial number, must be filed on ATF Form 1678. Revised formulas for articles made with specially denatured alcohol or rum must be submitted on ATF Form 1479-A.

Inquiries. Inquiries concerning this circular should refer to its number and be addressed to the Assistant Director, Regulatory Enforcement, Bureau of Alcohol, Tobacco and Firearms, 1200 Pennsylvania Avenue, NW., Washington, DC 20226.



Rex D. Davis
Director

Department of the Treasury
Bureau of Alcohol, Tobacco and Firearms
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